

### **REMARKS**

In view of the following remarks, the Examiner is requested to allow Claims 9-16 and 34-37, the only claims pending and under examination in this application.

Claim 9 has been amended to clarify the claim language. Claims 16 and 34 have been amended to correct minor informalities. Accordingly, no new matter has been added. As no new matter has been added by way of these amendments, entry thereof by the Examiner is respectfully requested.

The Applicants gratefully acknowledge the Examiner's indication that Claims 34-37 are allowed.

### ***Claim Objections***

Claim 34 was objected to by the Examiner due to minor informalities, which Applicants have corrected by amendment. As such, this objection may be withdrawn.

### ***Claim Rejections – 35 U.S.C. § 112, second paragraph***

Claim 16 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As indicated above, Claim 16 has been amended such that it now depends from Claim 15. As such, the Applicants submit that Claim 16 satisfies the requirements of 35 U.S.C. § 112, second paragraph, and this rejection may be withdrawn.

### ***Claim Rejections – 35 U.S.C. § 102***

Claims 9-14 and 16 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Weinberger et al. (U.S. Patent Publication No. 2004/0248318).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631; 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

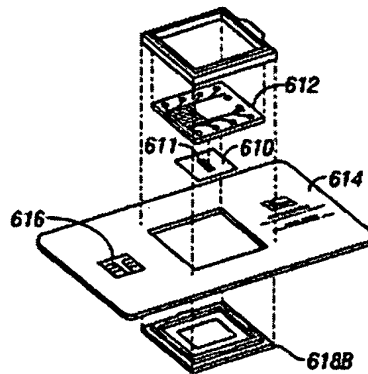
Claims 10-14 and 16 ultimately depend from Claim 9. Claim 9 is directed to an assay device. The claimed device includes a base, a cover, and a clamping member for holding the cover to the base. In addition, the device includes a flexure or spring element that interacts with the clamping member.

The claimed assay device is configured such that the clamping member upon actuation applies a force to the cover and base in a manner sufficient to produce a substantially uniform distance between an array assembly and backing element along the entire length of the cover and base when the array assembly and backing element are present in the device.

In maintaining this rejection, the Examiner asserts that the Weinberger device includes the same elements as recited in the Applicants' claims, and that these elements are capable of interacting in the same manner to produce the same result.

The Applicants respectfully disagree. In making this rejection, it appears the Examiner has not given patentable weight to the claimed flexure or spring element. The Examiner has not set forth where in Weinberger the recited flexure or spring element is taught. Rather, the Examiner assumes that simply because the Weinberger device includes a base, a cover, and a clamping member that Weinberger anticipates the Applicants' claims.

The Applicants respectfully disagree and contend that Weinberger does not disclose any element equivalent to the flexure or spring element recited in the Applicants' claims. As shown in FIG. 6A below, Weinberger discloses an array substrate (610) and a manifold (612) held together by a two-piece bezel (618A, 618B). See also Weinberger, pg. 7, paragraph [0116]. However, nowhere does Weinberger disclose the claimed element of a flexure or spring element. Thus, for this reason alone this rejection may be withdrawn.



**FIG. 6A**

Additionally, the Examiner erroneously assumes that simply because Weinberger allegedly discloses some elements similar to those recited in the Applicants' claims that the Weinberger device inherently anticipates the Applicants' claimed invention. The Applicants respectfully disagree and contend that the elements of the claimed assay device interact with one another in a manner sufficient to produce a substantially uniform distance along the entire cover and base. Specifically, the flexure or spring element interacts with the clamping member such that when the clamping member is actuated a force is applied to the cover and base in a manner sufficient to produce a substantially uniform distance between an array assembly and backing element along the entire length of the cover and base when the array assembly and backing element are present in said device.

However, nowhere does Weinberger disclose that the two-piece bezel (i.e., clamping member) is capable of being actuated to apply a force to the cover and base in a manner sufficient to produce a substantially uniform distance between an array assembly and backing element along the entire length of the cover and base when the array assembly and backing element are present in said device.

In view of the above, the Applicants contend that Weinberger does not anticipate the rejected claims because Weinberger does not teach all the elements of the rejected claims. The Applicants, therefore, respectfully request that the 35 U.S.C. § 102(e) rejection of Claims 9-14 and 16 be withdrawn.

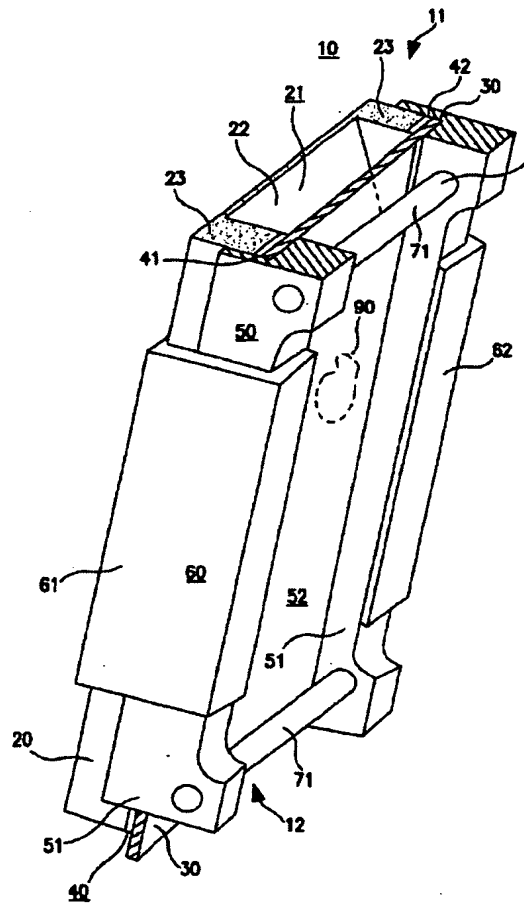
Claims 9-16 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Eichele et al. (U.S. Patent No. 6,623,701).

Claims 10-16 ultimately depend from Claim 9. The elements of Claim 9 are set forth above.

Similar to Weinberger above, in maintaining this rejection, the Examiner asserts that the Eichele device includes the same elements as recited in the Applicants' claims, and that these elements are capable of interacting in the same manner to produce the same result.

The Applicants respectfully disagree. In making this rejection, it appears the Examiner has not given patentable weight to the claimed flexure or spring element. The Examiner has not set forth where in Eichele the recited flexure or spring element is taught. Rather, the Examiner assumes that simply because the Eichele device includes a base, a cover, and a clamping member that Eichele anticipates the Applicants' claims.

The Applicants respectfully disagree and contend that Eichele does not disclose any element equivalent to the flexure or spring element recited in the Applicants' claims. As shown in FIG. 1 below, Eichele discloses a base plate (20), a specimen carrier plate (30), and a frame arrangement (50) held together by a clamping device (60). See also Eichele, col. 4, lines 59-67. However, nowhere does Eichele disclose the claimed element of a flexure or spring element. The Examiner alleges that the cover and the base of Eichele are flexures. See July 11, 2007 Office Action, pg. 4. However, Eichele actually discloses that "[t]he base and carrier plates, made of glass, do not undergo any deformation at all in the temperature ranges of interest, below 100°C". See Eichele, col. 3, lines 52-54. Thus, Eichele does not disclose, and in fact teaches away from, the flexure or spring element claimed in the instant invention. Consequently, for these reasons alone this rejection may be withdrawn.



**FIG. 1**

Additionally, the Examiner erroneously assumes that simply because Eichele allegedly discloses some elements similar to those recited in the Applicants' claims that the Eichele device inherently anticipates the Applicants' claimed invention. The Applicants respectfully disagree and contend that the elements of the claimed assay device interact with one another in a manner sufficient to produce a substantially uniform distance along the entire cover and base.

However, nowhere does Eichele disclose that the clamping device (60) is capable of being actuated to apply a force to the cover and base in a manner sufficient to produce a substantially uniform distance between an array assembly and backing element along the entire length of the cover and base when the array assembly and backing element are present in said device. In fact, as illustrated in FIG. 4 below, Eichele actually discloses that "the base plate 20 is designed to be

inclined obliquely in the centre so as to form a liquid reservoir **21**, so that a wedge shaped ramp is formed", creating a ramp area (22). See also Eichele, col. 5, lines 15-23. Thus, the specimen chamber of Eichele does not disclose a substantially uniform distance between an array assembly and backing element along the entire length of the cover and base, and in fact teaches away from this element because Eichele discloses that the base plate is obliquely angled at one end.



**FIG. 4**

In view of the above, the Applicants contend that Eichele does not anticipate the rejected claims because Eichele does not teach all the elements of the rejected claims. The Applicants, therefore, respectfully request that the 35 U.S.C. § 102(e) rejection of Claims 9-16 be withdrawn.

***Claim Rejections - 35 U.S.C. § 103***

Claims 9-11 and 14-16 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bowen (U.S. Patent No. 5,053,197) in view of Eichele.

In order to meet its burden in establishing a rejection under 35 U.S.C. § 103 the Office must first demonstrate that the combined prior art references teach or suggest all the claimed limitations. See *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007) ("the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would

have had reason to attempt to make [every element of] the composition or device, or carry out the [entire] claimed process, and would have had a reasonable expectation of success in doing so," (*citing KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007))); and see *Omegaflex, Inc. v. Parker-Hannifin Corp.*, 2007 U.S. App. LEXIS 14308 (Fed. Cir. 2007) ("[t]he Supreme Court recently explained that 'a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art,'" (*citing KSR Int'l Co. at 1741*)); and see *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006) ("[once] all claim limitations are found in a number of prior art references, the factfinder must determine '[w]hat the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references,'" (*citing In re Fulton*, 391 F.3d 1195, 1199-1200 (Fed. Cir. 2004))).

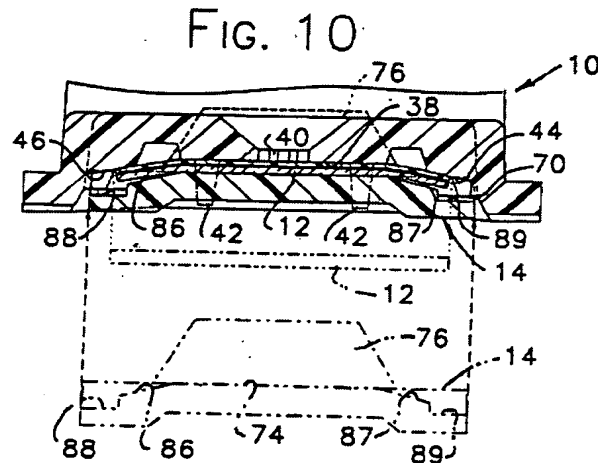
As set forth above, an element of the rejected claims is a flexure or spring element.

The Examiner alleges that Bowen discloses an assay device comprising a base, a cover, and a flexure. However, the Examiner concedes that Bowen is deficient in that Bowen fails to disclose a clamping member. To remedy the deficiencies in Bowen, the Examiner relies upon Eichele.

The Applicants respectfully disagree and contend that a *prima facie* case of obviousness cannot be maintained because the cited combination of references fails to teach or suggest all the elements of the claimed invention. Specifically, the Applicants submit that neither Bowen nor Eichele teach or suggest the claimed element of a flexure or spring.

As shown in FIG. 10 below, Bowen is directed to an assay module that includes a bottom member (14), an assay element (12), and a top member (10) with a fluid transport surface (38). See also Bowen, col. 4, lines 17-21, and col. 5, lines 28-31. When the assay module is assembled, "a combination of the ramps **86, 87** on the bottom member and the complementing inclination of the ramps **44, 46** in the

top member result in a flexure of the assay element 12". See Bowen, col. 8, lines 48-52. Thus, Bowen does not disclose or suggest a separate flexure or spring element, but rather merely contains a description that the assay element (12) is flexed against the fluid transport surface (38) during assay module assembly. See Bowen, col. 3, lines 32-35.



As discussed above, Eichele also fails to disclose the claimed element of a flexure or spring. Moreover, Eichele fails to suggest a flexure or spring element because Eichele discloses that the base and carrier plates do not undergo any deformation at all. Accordingly, Eichele is deficient in that it fails to suggest a flexure or spring element. Thus, Eichele fails to remedy the deficiencies of Bowen set forth above.

Consequently, the Applicants contend that the cited combination of Bowen and Eichele fails to teach or suggest all the elements of the claimed invention. Therefore, the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claims 9-11 and 14-16 be withdrawn.




**CONCLUSION**

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Bret Field at (650) 833-7770.

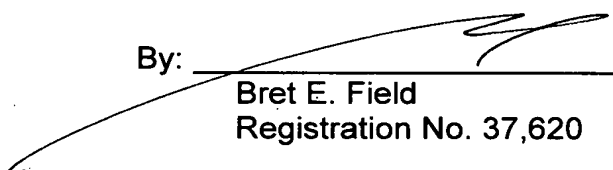
The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078.

Respectfully submitted,

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